Section C. Cost Determination and Assignment

General Instructions:
The information you provide by completing the Cost Assignment Sheet (see next page) will be used to determine resource utilization and cost of CTRC resources and to identify the person(s) responsible for specific costs.

Protocol Categorization:
Determination as to what extent a research project will be supported will be determined by the CTRC Oversight Committee. A research protocol is designated as one of the following categories:

<table>
<thead>
<tr>
<th>Category B Studies</th>
<th>Category C Studies</th>
<th>Category D Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study initiated by a Early-Stage Investigator (NIH/Grant, Foundation, Department sponsored, Network studies, or unfunded research)</td>
<td>Study initiated by an investigator (NIH/Grant,Foundation, Network studies, Department sponsored, or unfunded research)</td>
<td>Study initiated by an investigator or industry and sponsored by industry</td>
</tr>
</tbody>
</table>

Definition of Early-Stage Investigator:
A Principal Investigator is considered an “Early Stage Investigator” if he/she is within 10 years of completing his/her terminal research degree or is within 10 years of completing medical residency (or the equivalent).

Investigator-initiated Protocols:
Investigator-initiated studies are generally funded by a non-profit, state, or government agency; however in some cases, studies may also receive industry funding. For multi-center studies, UNC does not have to be the coordinating center; however, the research must meet all of the following criteria to receive a designation as an Investigator-initiated protocol:

- The research is within the investigators’ area(s) of academic research interest.
- The investigator(s) have had substantial input into protocol design for the proposed protocol and take responsibility for the quality of the protocol.
- The principal investigator will have full control of the data and will be the responsible author for all major publications that result from the research.

IMPORTANT: For information or assistance in completing the Cost Assignment Sheet, please contact Leslie Powell, 919-843-0267, leslie_powell@med.unc.edu.
Billing and Cost Assignment Sheet: Please Read Instructions

<table>
<thead>
<tr>
<th>Protocol Number:</th>
<th>Title of Study:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator:</td>
<td>Telephone #:</td>
</tr>
<tr>
<td>Study Coordinator:</td>
<td>Telephone #:</td>
</tr>
<tr>
<td>Departmental billing /Cost Sheet contact:</td>
<td>Telephone #:</td>
</tr>
</tbody>
</table>

Is this study (choose one): [ ] *Investigator initiated [ ] Industry initiated
* Investigator-initiated studies must meet ALL of the four criteria listed in the instructions.

Are you (choose one): [ ] *Early-Stage investigator [ ] *Senior investigator
*Refer to definitions in the instructions.

Are you requesting Research on Location (CTRC staff comes to in-patient hospital or outpatient clinic setting)?
[ ] Yes [ ] No

Please indicate ALL funding sources that will pay for this study (check all that apply):
[ ] Federal funds [ ] Industry funds [ ] Other (foundation, dept, etc.)
If Other, name funding source:

Are you applying for TraCS Pilot Funding? [ ] Yes [ ] No
If yes, have you received APPROVAL for funding? [ ] Yes [ ] No
If yes, FUNDING AMOUNT: $

Total number of subjects: Estimated duration of study (i.e., subject interaction): years

Number of outpatient subjects: Number of outpatient clinic visits/subject:
Number of inpatient subjects: Number of inpatient NIGHTS/subject:

REQUEST FOR TESTS, PROCEDURES, MEDICATIONS AND/OR SUPPLIES

<table>
<thead>
<tr>
<th>Name of Test/Procedure (e.g., Lab, CXR, Dexascan, lidocaine, etc)</th>
<th>Number per Subject</th>
<th>Lab or Department performing test</th>
<th>Test/Procedure billed to:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Subject/Insurance</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Investigator 98 Account</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>CTRC</td>
</tr>
</tbody>
</table>

1. DO NOT list “kit” labs (i.e., those being sent to a Central lab) or other non-billable tests and/or procedures for which the Sponsor has provided you with materials and/or equipment.

2. Examples: McLendon Labs, Investigator Lab, Body Composition, Cardiology, Pulmonary or Core Facility Labs.

   PLEASE NOTE: “Core Lab” refers to UNC core facilities that provide support for clinical investigators, not McLendon Core Lab.

3. CTRC should not be chosen for any study approved after September 1, 2009. No Costs will be paid for by the CTRC if approved after this date.

98 Account Number for Investigator charges: 98#: 

PI Signature: ___________________________ Date: ___________________________

CTRC Approval Signature: ___________________________ Date: ___________________________
Category of research for billing purposes (*Designation to be made by CTRC*): ____________________